-Remarks-

Amendments.

Applicants respectfully request entry of the above amendments and reconsideration and withdrawal of the rejection of claims 1 - 11.

The 35 U.S.C. §112, first paragraph, rejection.

The Examiner has rejected claim 11 under 35 U.S.C. §112, first paragraph, alleging that the specification does not reasonably provide enablement for treating a mammal for asthma, chronic obstructive pulmonary disease, allergic rhinitis, and infectious rhinitis. Specifically, the Examiner has alleged that claim 11 is not enabled because the specification does not disclose any data. Applicant respectfully traverses.

The Examiner has stated on page 3 of the office action that US Patent Nos. 6,262,115; 5,674,895; 5,840,754 and 5,912,268 disclose that "the claimed compound I can be used for treating urinary incontinence, while there is no other effect on other diseases." Applicant has enclosed a copy of each of the referenced patents. Applicant submits that the compounds of claim 1, and the compounds used in the method of claim 11, of the instant invention, i.e., compounds which are quaternary ammonium salts of oxybutynin, are not disclosed in any of the above-referenced patents. As will be clearly set forth later in this response, the only compounds disclosed in those patents are oxybutynin and desethyloxybutynin. Neither of these compounds are within the scope of the method of claim 11 of the instant invention.

Applicant submits that data is not required to enable the method claim of the instant invention, which is directed to a method of treating four related respiratory conditions with a very limited number of compounds. At page 9, line 28 to page 10, line15 of the specification, Applicant discloses an assay which can be used to demonstrate the bronchodilatory effect of the compounds of this invention. Applicant submits that this assay is a well established predictor of bronchodilatory activity. Further, compounds which are bronchodilators are known to treat asthma, chronic obstructive pulmonary disease, allergic rhinitis, and infectious rhinits. In fact, there are various bronchodilators already on the market and being used to treat the above conditions with varying degrees of success, including theophylline for the treatment of asthma and tiotropium for the treatment of asthma and chronic obstructive pulmonary disease.

Applicant submits that claim 11 is enabled and respectfully requests that the Examiner reconsider and withdraw the 35 U.S.C. §112, first paragraph, rejection of claim 11.

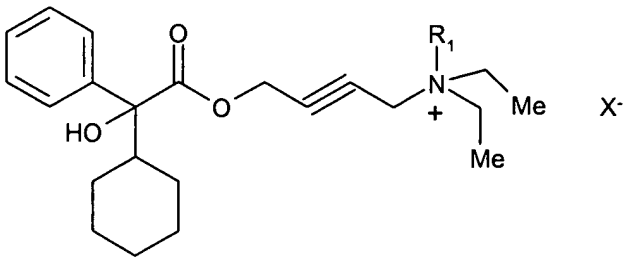
The 35 U.S.C. §102 rejection.

The Examiner has rejected claims 1 - 2, 7 and 9 - 10 as being anticipated by Guittard, US Patent No. 5,840,754 ("the '754 patent"). The Examiner has alleged that 2-butyn-1-amminium, 4-[(cyclohexylhydroxyphenylacetyl)oxy]-N,N-diethyl-N-methyl, nitrate is disclosed at column 10, lines 45 - 67 of the '754 patent. Applicant respectfully traverses.

1. The instant claims.

The instant invention claims compounds which are quaternary ammonium salts of oxybutynin. These quaternary ammonium salts are characterized by having four covalent bonds to nitrogen, resulting in a positive charge on the nitrogen which must

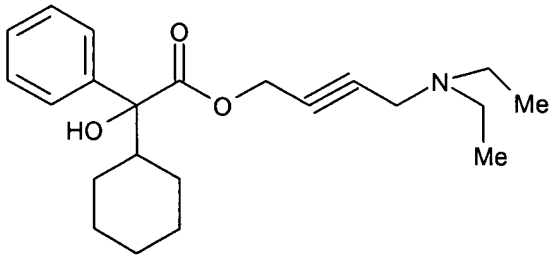
be countered with an anion, represented by X^-. The compounds of the instant invention have the following structure, which clearly shows that there are four covalent bonds on the quaternary nitrogen:



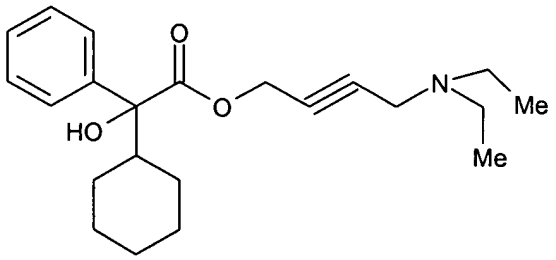
2. The '754 patent.

The '754 patent discloses oxybutynin, oxybutynin hydrochloride, and desethyloxybutynin. These compounds have the following chemical structures:

oxybutynin:

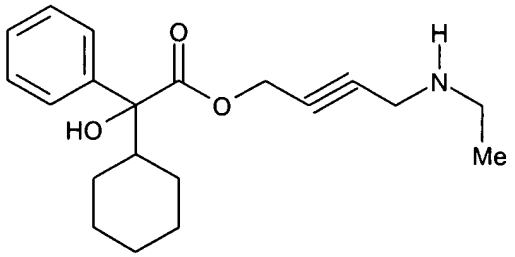


oxybutynin hydrochloride:



·HCl

desethyloxybutynin:



3. The '754 patent does not anticipate the instant claims.

Applicant submits that the '754 patent does not disclose 2-butyn-1-aminium, 4-[(cyclohexylhydroxyphenylacetyl)oxy]-N,N-diethyl-N-methyl-, nitrate. In fact, the '754 patent mentions only two compounds, oxybutynin (designated "OXY" in the paragraph beginning at column 10, line 45) and desethyloxybutynin (designated "DESOXY" in the paragraph beginning at column 10, line 45). From inspection of these compounds and comparison to the instant compounds, it is clear that neither of them is within the scope of claim 1 or any other claim in the instant application. Accordingly, Applicant submits that claims 1, 2, 9 and 10 are not anticipated by Guittard. Applicant respectfully requests that the Examiner reconsider and withdraw the 35 U.S.C. §102 rejection of claims 1, 2, 9 and 10.

The 35 U.S.C. §103 (a) rejection.

The Examiner has rejected claims 1 - 10 under 35 U.S.C. §103(a) as being obvious over the '754 patent. Specifically, the Examiner has alleged that the '754 patent discloses 2-butyn-1-aminium, 4-[(cyclohexylhydroxyphenylacetyl)oxy]-N,N-diethyl-N-methyl-, nitrate at column 10, lines 45 - 67 and that the '754 patent also discloses oxybutynin hydrobromide and oxybutynin hydrochloride at column 3, lines 36 - 40. Applicant respectfully traverses.

Applicant submits that the compounds of claim 1, including 2-butyn-1-aminium, 4-[(cyclohexylhydroxyphenylacetyl)oxy]-N,N-diethyl-N-methyl-, nitrate are not obvious over the disclosure made by the '754 patent. There is no teaching or suggestion that oxybutynin would have any activity if the nitrogen atom would be tied up completely by a fourth covalent bond. The '754 patent mentions the hydrochloric acid salt of oxybutynin. This does not suggest the instant compounds since a person of ordinary skill in the art would not be motivated by the disclosure of a hydrochloride salt of a tertiary amine to make a quaternary ammoniuim salt thereof. The properties of a quaternary ammonium salt would be considered by a person of ordinary skill in the art to be too different from the properties of a hydrochloride salt of a tertiary ammonium compound, primarily due to the presence of a fourth covalent bond to nitrogen which would be expected to exert profound changes upon the chemical and biological properties of the compound.

In fact, the '754 patent teaches away from adding another covalent bond to the amino group in oxybutynin. The '754 patent discloses desethyloxybutynin, which is similar to oxybutynin with one exception: it has one less covalent bond to nitrogen. Accordingly, the '754 patent would lead a person of ordinary skill in the art to expect that adding another methyl or other covalently bonded group to the nitrogen atom would be less active than oxybutynin or desethyloxybutynin.

The Examiner has given the example that "if the skilled artisan in the art had desired to make the quaternary ammonium salt based on iodine, it would have been obvious to the skilled artisan in the art to have [*sic*, been] motivated to select the iodide anion as an alternative to the other pharmaceutically acceptable anions, such as bromide and chloride

Accordingly, Applicant submits that the instant claims are nonobvious over the '754 patent. Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection of claims 1 - 10.

- Conclusion -

Having addressed all points and concerns raised by the Examiner, Applicants believe that this application is in condition for allowance. An early and favorable action is respectfully requested.

Respectfully submitted,

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